



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Alan Morris
Manager, Product Development
MedTox Diagnostics, Inc.
1238 Anthony Road
Burlington, North Carolina 27215

NOV 10 2003

Re: k033334
Trade/Device Name: Profile® -ER TCA/BAR/BZO
Regulation Number: 21 CFR § 862.3150
Regulation Name: Barbiturates
Regulatory Class: II
Product Code: DIS, JXM, LFG
Dated: October 14, 2003
Received: October 20, 2003

Dear Mr. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

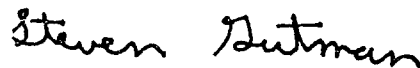
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k)
Number
(if known)

K033334

Device Name Profile®-ER TCA/BAR/BZO

Indications for Use

The 3 Panel TCA/BAR/BZO is a one-step immunochromatographic test for the rapid, qualitative detection of tricyclic antidepressants, barbiturates and benzodiazepines and their metabolites. The test detects the major metabolites of these drugs at the following cutoff concentrations:

Tricyclic antidepressants (Desipramine) - 50 ng/ml

Barbiturates (Phenobarbital)-200 ng/ml

Benzodiazepines (Nordiazepam)-300 ng/mL

This product is not for over-the-counter-sale

The 3 Panel provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ (Per 21 CFR 801. 109)

OR

Over-The-Counter Use ☐

Division Sign-Off

Carol C. Benson for Jean Cooper, DVM

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K033334